

ONLINE

# USPTO TODAY

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## August is National Inventors' Month

The first National Inventors' Month was established in 1998 by INVENTORS' DIGEST Magazine, the United Inventors Association of the USA, and the Academy of Applied Science to "put the spotlight on inventors."



## *In Touch*

*With the Under Secretary for IP*

**Q. Todd Dickinson**  
Under Secretary of Commerce for Intellectual Property and  
Director of the United States Patent and Trademark Office

Welcome to the August edition of *USPTO Today*. While the summer months can sometimes seem unhurried, the USPTO certainly shows no sign of slowing. In fact, this month saw a major initiative finally come to fruition: the creation of two new USPTO advisory panels, the Patent Public Advisory Committee and the Trademark Public Advisory Committee. These panels will advise my office on agency operations, goals, performance, budget issues and user fees. I'm excited about these inaugural appointments and wanted to use this month's column to introduce the committee chairs and members.

But first, some background. I know many of you are familiar with 1999's groundbreaking intellectual property legislation, the American Inventors Protection Act. It was this act that allowed the committees' establishment, with the statute designating that each would have nine voting members, appointed by the secretary of Commerce, and non-voting membership for the agency's three recognized unions.

With that mandate in hand, the secretary approved our appointments this past July, and we're scheduled for our first meeting this August 23. I'm pleased to report that they are a truly diverse group, ranging from independent inventors to academicians to small entrepreneurs to corporate executives. We'll be working with attorneys, specialists in labor relations, and experts in management, finance, science, technology, and, of course, intellectual property issues. They will offer us breadth and depth of experience, and I believe that they represent the variety of groups we work with every day here at the USPTO.

A brief rundown on our new panel members:

The **Patent Public Advisory Committee** will be chaired by **Margaret (Meg) Boulware**, a partner with the Houston, TX firm of Jenkins & Gilchrist, and immediate past president of the American Intellectual Property Law Association. Her experience encompasses patent prosecution and litigation as well as international trademark and domestic copyright practice. Ms. Boulware will be joined by:

**James L. Ferguson** of Redwood City, CA, an independent inventor and developer of the field effect liquid crystal display that is used in most digital watches. He holds more than 50 U.S. patents, and is an inductee of the Inventor's Hall of Fame. Mr. Ferguson is also a small business owner, as the founder and CEO of International Liquid Crystal Company (ILIXCO).

**Andy Gibbs** of Yuba City, CA, an independent inventor and entrepreneur, is the founder and CEO of PatentCafe.com, an Internet portal for inventors, which helps foster small entity intellectual property development and commercialization. With five U.S. patents, he has launched several intellectual property based businesses, ranging from medical technology to electronics and sports accessories.

**Patricia W. Ingraham** of Binghamton, NY, is the director of the Alan K. Campbell Institute for Public Affairs at Syracuse University and distinguished university professor at the Maxwell School of Citizenship and Public Affairs. She is a widely published author on the subject of public management and served as a member of the vice president's Committee on Customer Service in 1999. At the Maxwell School, she directed the Government Performance Project which graded cities and federal agencies, including the USPTO, on their performance.

**Roger L. May** of Dearborn, MI, is the president, CEO and general counsel of Ford Global Technologies, Inc., which owns and manages Ford Motor Company's major automotive intellectual property assets. With overall responsibility for managing intellectual property rights for Ford, he also oversees Ford's Technology Venture Fund and its Patent and Technology Licensing Office.

**Gerald J. Mossinghoff** of Arlington, VA, is senior counsel to the firm of Oblon, Spivak, McClelland, Maier & Neustadt. A visiting professor of intellectual property at the George Washington University School of Law, Mr. Mossinghoff formerly served as assistant secretary of Commerce and commissioner of patents and trademarks.

**Ronald E. Myrick** of Weston, CT, is the chief intellectual property counsel for the General Electric Company. He is the president of the Intellectual Property Owners Association (IPO) and chairs the IPO Task Force on Business Method Patents. He is an officer of both the American Bar Association Intellectual Property Section, and the American Intellectual Property Law Association and is active in a number of other national and international intellectual property organizations.

**Vernon A. Norviel** of San Jose, CA, is the vice president and general counsel of Affymetrix, a bioinformatics company which is the developer of "DNA chip" technology — semiconductors with thousands of DNA probes for use in pharmaceutical research and diagnostic applications, exemplifying the convergence of computing and biotechnology.

**Katherine E. White** of Ann Arbor, MI, is an elected member of the University of Michigan Board of Regents and an assistant professor of law at Wayne State University in Detroit, MI, teaching patent law and enforcement. In 1999, Professor White was the recipient of a Fulbright Senior Scholarship Award to the Max Planck Institute for Foreign and International Patent, Copyright and Competition Law in Munich, Germany. She also serves as a reserve major in the Judge Advocate General (JAG) and is an instructor at the JAG School in Charlottesville, VA.

Our **Trademark Public Advisory Committee** will be headed by **Miles J. Alexander**, a senior partner in the Intellectual Property Group and chairman of Kilpatrick Stockton LLP, Atlanta, GA. He is former counsel to the International Trademark Association (INTA). Members of this panel include:

**Helen M. Korniewicz** of Corte Madera, CA, manages the trademark group at the Chevron Corporation Law Department. In addition to foreign and domestic trademark and copyright issues, she is responsible for legal services for the e-commerce and communications activities of several Chevron entities and has extensive experience in commercial and consumer credit services.

**Susan C. Lee** of Bethesda, MD, is of counsel to the firm of Pena & Associates, P.C. and specializes in trademarks, copyrights, trade secrets, unfair competition, and internet law. From 1988-1993, she served as a trademark attorney with the United States Patent and Trademark Office, including representing the USPTO before the U.S. Trademark Trial and Appeal Board.

**David M. Moyer** of Terrence Park, OH, is the associate general counsel for trademarks and trade relations at the Procter and Gamble Company. He is also a past board member of the International Trademark Association (INTA)

**Joseph Nicholson** of New York, NY, is a partner at Kenyon & Kenyon whose principal practice is trademark and unfair competition, including large international trademark portfolios. In addition to trademark practice, licensing and litigation, he has significant background in internet commerce and domain name issues.

**Louis T. Pirkey** of Austin, TX, is a member of the firm of Fulbright and Jaworski in Austin, TX. He currently serves as the president of the American Intellectual Property Law Association and is adjunct professor of trademark law at the University of Texas School of Law.

**Griffith B. Price, Jr.** of Bethesda, MD, is a partner at the firm of Finnegan, Henderson, Farabow, Garrett & Dunner, L.L.P. He specializes in trademark and unfair competition matters. He is the former chair of the USPTO Public Advisory Committee for Trademarks, and the founding chair of the American Intellectual Property Law Association (AIPLA) Trademark Law Practice Group.

**John T. Rose, II** of White Plains, NY, is vice president for human resources at ESPN. He previously served as senior vice president for player relations and administration for the NBA, where he was responsible for brand protection and trademarks worldwide, and organized an industry-wide task force on intellectual property protection. Prior to that, as vice president for law at NBC, he providing legal services on human resources, labor relations, finance, operations, and engineering matters.

**David C. Stimson** of Rochester, NY, is the chief trademark counsel for the Eastman Kodak Company. He has worldwide responsibility for Kodak's trademarks, including clearance, registration, oppositions, litigation, and licensing. He is a past president of the International Trademark Association and has chaired INTA's Legislation, Finance, and Planning Committees.

## USPTO Has a New Logo

The dynamic relationship between government, commerce, and invention is reflected in the new logo of the United States Patent and Trademark Office.



The eagle and its positioning conveys governmental protection and promotion of creativity and innovation as symbolized

by the light bulb. The four stars represent the support for intellectual property rights in America spanning four centuries from the Colonial period to the present.

Taken in its entirety, the logo illustrates the mandate of Article 1, Section 8, of the United States Constitution that “Congress shall have power . . . to promote the progress of science and useful arts by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries,” the very foundation of our Nation’s intellectual property system.

## Diversity: The Strength of a Workplace In Which All Employees Can Succeed

*by Francine Samuelson, Office of Human Resources*

According to “Best Practices in Achieving Workforce Diversity,” a joint benchmarking study by the Department of Commerce and the National Partnership for Reinventing Government,” it is imperative to value and recognize diversity in order to sustain an advantage in productivity, effectiveness, and sustained competitiveness in today’s work environment. The study maintains that organizations that promote and achieve a diverse workforce will attract and retain quality employees and increase customer loyalty. For public organizations, such as the USPTO, it also translates into effective delivery of essential services to communities with diverse needs.

The key finding of the study is that diversity needs to be defined broadly and should encompass a wide range of initiatives that meet the changing needs of customers and workers. Leaders and employees should take active roles in implementing diversity processes which, in order to succeed, should be fully aligned with core organizational goals and objectives. The benefits of diversity are for everyone. Diversity is more than a moral imperative; it is a global necessity. Moreover, diversity is an essential component of any civil society.

According to Kimberly Walton, deputy chief administrative officer of the USPTO, the key to managing a diverse workforce is “to create a worklife environment in which any employee can succeed.” Walton stresses that today, “diversity is not just equal employment opportunity or civil rights. Rather, we want to meet this administration’s goal of having a workforce that ‘looks like America.’ We want to level the playing field so that all employees have the opportunity to succeed.”

“The USPTO has a strong commitment to inclusion” said Under Secretary Dickinson. “It has been a leader in helping the federal workforce to be more reflective of the rich diversity of America,” he continued. “It has a legacy that goes back over 150 years, not long after the birth of the women’s rights movement, when our office became the first federal agency to employ female clerks. Today, we are one of the most diverse--if not the most diverse--agencies in the federal government.”

Commissioner for Patents Nick Godici has been with the USPTO since 1972, and has seen a major cultural change happen over the past 28 years. He comments that “Our workforce, one of the most diverse and best educated in government, reflects not only the rich diversity of our customers, but also of this nation. This commitment

**Clara Barton** was the first woman to be employed as a Patent Office clerk. She was hired in 1854 by Commissioner Charles Mason as a temporary copyist for 10 cents per 100 words, but quickly became a recording clerk.

*“I was placed equal with the male clerks at \$1,400 per year. This called for some criticism and no little denunciation on the part of those who foresaw dangerous precedents.”*

She worked at the Patent Office until Mason’s departure in 1857, even though his boss, Secretary of the Interior Robert McClelland, opposed female federal employment and found “the sight of teapots and hoop skirts” very annoying. She returned in 1860, only to be called away to minister to wounded Civil War soldiers. She remained on the register, receiving half salary, until she resigned in 1865. Clara Barton went on to found the American Red Cross in 1882.

to inclusion not only benefits the agency but also our customers.”

Diversity is valued at all levels of the organization. At the higher levels of USPTO management have been the appointments of Esther Kepplinger as the first female deputy commissioner for patent operations, and the appointment of Anne H. Chasser as the commissioner for trademarks.

Chasser has remarked that, “I believe that I am here today because of the agency’s commitment to diversity, and I have a personal and professional obligation to embrace and promote diversity within the agency.” Chasser, who has been with the USPTO just since September 1999, gives her first impressions of diversity at the USPTO this

way: “Coming from a comprehensive, research institution where diversity and academic freedom was highly valued, I was pleasantly surprised to find that the USPTO truly demonstrates a commitment to diversity. One of the first meetings I attended was the Hispanic subcommittee meeting, and I was impressed with Under Secretary Dickinson’s open communication among under-represented groups. At the end of the day, I believe that we end up with a much stronger work product when we are inclusive. The key is that we operate in an atmosphere of mutual respect and trust. This agency is committed to diversity and ‘walks the talk’ through its many initiatives and support activities.”

The agency has a long history of highly competent women at the head of the trademark operation. About the time the U.S. Patent Office became the U.S. Patent and Trademark Office, Daphne Leeds was appointed as the first assistant commissioner for trademarks. Margaret Laurence held the position from 1980 to 1986.

### **A culturally diverse workforce that “looks like America.”**

Since 1991, the percentage of African-Americans at USPTO has remained around 35 percent, compared to 10.3 percent in the civilian labor force. Since 1991, the percentage of Asians/Pacific Islanders at the USPTO has increased tremendously from about 7 percent to 17 percent, compared to 2.8 percent in the CLF. Since 1994, the percentage of females in grades above GS-15 has increased greatly from 9.5 percent to 21.5 percent.

One area in which the USPTO needs to do better is in the recruitment of Hispanic Americans. The agency’s current workforce is 2.6 percent Hispanic, while the CLF is 8 percent Hispanic. This is a government-wide problem, and the administration has made it clear that all agencies need to do their share in reducing the underrepresentation of Hispanics in the federal workforce.

*The civilian labor force (CLF) statistics are based on the 1990 Census. PTO stats are current as of May 2000.*

The NPR benchmarking study identified three core organizational goals for diversity. They are: maximizing workplace satisfaction for all employees; retaining a world-class workforce; and maintaining an environment of lifetime learning. In order to reach these goals, agencies need to have in place employee-friendly programs which will accommodate a diverse workforce.

The USPTO has taken steps in this area. For example:

- The Office of Civil Rights sponsors an annual Community Day during which employees celebrate the value of cultural diversity to the agency's corporate structure. It is a "live" demonstration of inclusion that recognizes all cultures at the USPTO.

- An anonymous, online Employee Communication Mailbox allows USPTO employees to ask anything they want, and have their questions answered by the agency's Quality Council.

- The USPTO's Labor Management Partnership Council, that includes representatives from management and all three employee unions, received Government Executive magazine's recognition of improvement.

- In an effort to show commitment to lifelong learning, the agency established PTO University in 1994. It is the college-credit arm of employee development that is free to all employees and develops employee skills and knowledge for the emerging jobs at the USPTO. One of the most unique aspects of PTO-U is that it reaches all segments of the agency, as enrollment represents employee levels from clerks to managers to senior executives. At this time, PTO-U is in partnership with five universities including Johns Hopkins, which was added this year.

- From March 1997 to March 1999, a work-at-home project was piloted as a "reinvention lab." The project tested the technical feasibility of providing access to office equipment and information databases to 18 examining attorneys working from their homes three days a week. The final evaluation report shows that the attorneys increased their productivity by significantly increasing their examination hours.

- One of the "day-one" initiatives of the USPTO as a performance-based organization is the implementation of a greatly expanded flexitime program. The office's operational hours, 5:30a.m. to 8p.m., not only increase staff availability to customers, but also provide greater flexibility for employees. One employee commented that the new flexitime program has allowed single parents to work

schedules that prevent their children from becoming “latchkey” kids. The program includes a midday flex, under which employees are able to leave work in the middle of the day to attend to personal matters, without being charged leave, and to return to work to complete their scheduled workday. This expanded program permits managers and employees to achieve their program goals, while simultaneously allowing employees to have more flexibility in scheduling their personal and family activities.

■ The recent establishment of the Lesbian, Gay, Bisexual, Transgender Program Subcommittee, under the Office of Civil Rights, addresses equal employment issues that may be an outgrowth of an employee’s sexual orientation.

Although the USPTO has made great strides in achieving an employee-friendly workplace, the agency is not resting on its laurels. The following initiatives for the near future will increase organizational support the workforce.

■ A “Diversity Council” will provide a forum for the exchange of ideas regarding diversity and related human resource concerns.

■ The “work-at-home” program will be expanded for up to 60 examining attorneys in the next year, and may be expanded as an alternative method for addressing ever-increasing filings and currently limited office space.

■ New consolidated office space in Alexandria, Virginia, will have training and conference centers, an on-site child care center, and a fitness center. These will help provide for a well-trained, accommodated, and healthy workforce. The new facility will be compliant with the Americans with Disabilities Act, and thus, will be more accessible for the disabled. (Scheduled move to new facility is late 2003/early 2004.)

The USPTO wants to be the workplace of the future, one that will attract and retain superior employees by offering a diverse and employee-friendly workplace where everyone will feel welcome, have their work and personal needs met, and produce excellent products and services for our customers.

*Kimberly Walton, Deputy Chief Administrative Officer, contributed to this article.*

# Implementing the “American Inventors Protection Act of 1999”

*by Robert Clarke, Office of Patent Legal Administration*

The “American Inventors Protection Act of 1999” was enacted on November 29, 1999, as part of Public Law 106-113 (Consolidated Appropriations Act for Fiscal Year 2000). The AIPA includes eight subtitles (A-H), which make both fundamental changes to the patent law and the United States Patent and Trademark Office, such as the publication of patent applications and providing a third party with expanded participation during reexamination, as well as relatively minor changes such as amending the limitation on damages for patent infringement of a “medical method” patent. The USPTO’s Web site ([www.uspto.gov](http://www.uspto.gov)) includes a site devoted to the AIPA. A complete copy of the legislation is available at the AIPA site.

Implementing these changes is made more challenging as the Subtitles, and often individual portions of a Subtitle, become effective on a variety of dates and the changes made applicable to only certain applications.

Since August of 1999, when a predecessor bill to the AIPA passed the House of Representatives, the USPTO’s patents operation has been working to implement the substantive patent provisions of the AIPA. Six rule packages and one *Official Gazette* notice have been published to implement, propose to implement, and to provide guidance regarding these provisions. At least one more *Official Gazette* notice is planned. Highlights of subtitles A-F and H and of each of the rule packages are given below, together with the publication dates and citations for the documents. The future implementation efforts are also described. Implementation of Subtitle G, the “Patent and Trademark Office Efficiency Act,” however, is not discussed here.

## **Subtitle A**

Subtitle A is entitled “Inventor’s Rights Act of 1999” and provides that the USPTO will make all complaints involving invention promoters, and any reply of the invention promoter publicly available. The statute also provides definitions of invention promoters together with statutory exceptions. It is important to note that Subtitle A of the AIPA, unlike some of the predecessor bills, does not provide a statutory exception for registered patent practitioners. Subtitle A became effective on January 28, 2000.

The USPTO has published an interim rule entitled “Complaints Regarding Invention Promoters” in the *Federal Register* at 65 *Fed. Reg.* 3127 (January 20, 2000) and in the Official Gazette at 1231 *Off. Gaz. Pat. Office* 37 (February 8, 2000). This rulemaking implements Subtitle A of the AIPA by establishing certain definitions, procedures to receive complaints concerning invention promoters, procedures to notify the alleged promoters, procedures for the alleged promoter to reply, and procedures to publish both the complaint and reply. The interim rules became effective on January 28, 2000, and the comment period for this rulemaking expired on February 22, 2000.

The rules define “invention promoter” as any entity who offers to perform or performs invention promotion services for a customer, and who holds itself out through advertising as providing those services. Exceptions to this definition are provided to exclude government entities, certain charitable organizations, and certain acts of others directed to traditional sales of intellectual property. For example, persons involved in the commercial potential of, or offering to license or sell, a utility patent or a previously filed nonprovisional application are excluded from the definition. “Invention promotion services” is defined as the procurement or attempted procurement for a customer to develop and market products or services that include the invention of the customer.

The rules establish procedures to accept complaints and to forward the complaint to the alleged invention promoter. The rules also provide procedures concerning the formal requirements of complaints and replies. The USPTO will not conduct any independent investigation of the invention promoter. The USPTO will, however, publish the complaint and any reply received, in the *Official Gazette*, the *Federal Register*, or electronically on the USPTO’s Internet home page.

A system for accepting and maintaining records of complaints against invention promoters and responses, and for publishing both, will be handled by the Office of the Independent Inventors Program.

### **Subtitle B**

Subtitle B is entitled “Patent and Trademark Fee Fairness Act of 1999.” This subtitle, in recognition that patent fee income of the USPTO was offsetting a portion of the costs of trademark operations, provided a decrease in both patent filing fees, and the first stage maintenance fee to provide for a proper allocation of costs between the patent and trademark operations. The statute also

provided that the USPTO could raise certain trademark fees to offset the decrease in revenues due to the lowered patent fees. The changes to the patent fees became effective on December 29, 1999, while the trademark fees established by rulemaking were effective on January 10, 2000.

A final rule entitled “Revision of Patent and Trademark Fees for Fiscal Year 2000” was published in the *Federal Register* at 64 *Fed. Reg.* 67774 (December 3, 1999) and in the *Official Gazette* at 1229 *Off. Gaz. Pat. Office* 38 (December 14, 1999). This rulemaking implements Subtitle B of the AIPA by raising certain trademark fees to offset the statutory lowering of patent filing and first maintenance fees. The rules related to the statutory changes to patent filing and first maintenance fees were also amended to conform to the new lower levels.

### **Subtitle C**

Subtitle C is entitled “First Inventor Defense Act of 1999.” This subtitle provides a limited defense to certain infringement actions where the asserted claim(s) is directed to a “business method” as defined in the AIPA. Since the USPTO is not required to change any of its procedures in view of the new defense to infringement actions, no rulemaking has been promulgated. Further the USPTO has not provided any guidance on what infringement actions would be subject to the defense, nor what evidence must be shown by the alleged infringer in order to successfully assert the defense.

### **Subtitle D**

Subtitle D is entitled “Patent Term Guarantee Act of 1999.” This subtitle provides for adjustment of the term of patents issuing from utility and plant applications filed on or after May 29, 2000, and for continued examination of utility and plant applications. The legislation provides three bases of adjustment. The first basis provides adjustment when the USPTO fails to act on an application within specified time periods. The second basis provides adjustment when the USPTO fails to issue a patent within three years of the actual filing date, subject to a number of statutory restrictions. The third basis provides adjustment for the time consumed by interferences, imposition of secrecy orders, and for successful appeals.

The statute requires the USPTO to reduce the patent term adjustment for the time during which an applicant failed to engage in reasonable efforts to conclude processing or examination of an application. The statute also requires the USPTO to prescribe regulations establishing the circumstances that would constitute such conduct.

A notice of proposed rulemaking entitled “Changes to Implement Patent Term Adjustment under Twenty-Year Patent Term” was published in the *Federal Register* at 65 *Fed. Reg.* 17215 (March 31, 2000) and the *Official Gazette* at 1233 *Off. Gaz. Pat. Office* 109 (April 25, 2000). This rule implements a portion of Subtitle D of the AIPA by proposing procedures for a patent term adjustment (extension) system that became effective May 29, 2000, and applies to patents resulting from applications filed on or after May 29, 2000. The comment period for this rulemaking expired May 30, 2000. The next step is to reconsider the proposed procedures and to adopt procedures for the patent term adjustment system by undertaking a final rulemaking process. Publication of the final rulemaking is anticipated before August 22, 2000.

The proposed rules indicate that only utility and plant applications filed on or after May 29, 2000, are eligible for the new patent term adjustment provisions. These rules provide for patent term adjustment according to the three statutory bases, and provide for the explicit statutory reduction. The rules also propose to implement the statutory requirement to define conduct where an applicant fails to engage in reasonable efforts to conclude processing or examination of an application by setting forth that the period of adjustment would be reduced by any period of time during which an applicant failed to engage in reasonable efforts to conclude prosecution. The rules also provide 17 specific circumstances that would define such conduct.

It is important to note that any utility or plant application that is filed on or after May 29, 2000, is subject to the new patent term adjustment statutory provisions. Any patent that issues after the final rules are effective will be subject to those final rules regardless of the status of the rules when the application was filed. Therefore, applicants should carefully review the proposed rules to avoid conduct that will be considered a failure to engage in reasonable efforts to conclude prosecution.

Subtitle D also requires the USPTO to prescribe regulations to provide for continued examination of utility and plant applications filed on or after June 8, 1995, at the request of applicants for a fee.

An interim rule entitled “Changes to Application Examination and Provisional Application Practice” was published in the *Federal Register* at 65 *Fed. Reg.* 14865 (March 20, 2000) and the *Official Gazette* at 1233 *Off. Gaz. Pat. Office* 47 (April 11, 2000). This rulemaking implements a portion of Subtitle D of the AIPA by establishing procedures for continued examination practice effective May 29, 2000, as well as a few miscellaneous provisions that

became effective on enactment of the AIPA. The comment period for this rulemaking expired May 19, 2000. The next step is to reconsider the interim rule in view of the public comments, and adopt final changes by undertaking a final rulemaking process. Publication of a final rule is expected by August 15, 2000. The effective date for any final rule will be the date of publication of the final rule.

The interim rules provide a procedure by which an applicant may file a request for continued examination (RCE), with a fee, and continue prosecution of an application regardless of the status of the prior office action in most circumstances. A RCE withdraws the finality of the last office action. Therefore, continued examination may be requested after a final rejection, an allowance, an appeal, or an action under *Ex parte Quayle*, 1935 Comm'r Dec. 11(1935). If a reply to the prior office action was due, the RCE must be accompanied by a reply in response to the last office action. Responsiveness of the reply is determined after the finality of the office action is withdrawn. Therefore, if an RCE is submitted in an application under a final rejection, the RCE must be accompanied by a reply that would be fully responsive to the merits of the final rejection if that final rejection had been a non-final rejection. If the reply is not fully responsive, but is a *bona fide* attempt to reply to the prior office action, the period for reply to the prior office action is tolled by the reply, and a new time period should be set to provide a complete reply. If the reply is neither fully responsive nor a *bona fide* attempt to reply to the prior office action, then the period for reply in the prior office action is **not** tolled.

The fee for filing a RCE is the basic filing fee for a utility application. This fee does not include additional claims fees previously paid for. Additional claims which would have required additional claims fees in the application prior to the RCE, which claims are submitted for the first time with the RCE, will require payment of additional claim fees, however.

Filing a RCE in an application after a notice of appeal, and prior to decision on that appeal, will be interpreted as a request to withdraw the appeal, regardless of the payment of the fee for the RCE or the presence of a submission. The result of filing such an RCE in an application with no claims indicated as allowable would be abandonment of the application. Similarly, if that RCE is filed in an application after a notice of appeal, and some of the pending claims were previously indicated as allowable, the USPTO would simply cancel the rejected claims, and pass the application to issue with only the previously allowed claims. Applicants, therefore, should be careful to provide both the appropriate fee, and a proper submis-

sion if an RCE is filed after a notice of appeal.

### **Subtitle E**

Subtitle E is entitled “Domestic Publication of Patent Applications Published Abroad Act of 1999.” This subtitle provides for the publication of most applications filed on or after November 29, 2000, 18 months after the earliest effective filing date or priority date claimed by the application. The statute also provides for the publication of only a portion of an application’s disclosure for applicants disclosing more subject matter in the U.S. application than in any corresponding foreign application. The statute also allows for publication of applications filed before November 29, 2000, at the request of an applicant and for publication of applications filed after that date earlier than 18 months after filing. The statute additionally provides for prior art treatment of published applications based on the application’s effective filing date. Provisional rights are available from the period of publication of the application to the issue date.

A notice of proposed rulemaking entitled “Changes to Implement Eighteen-Month Publication of Patent Applications” was published in the *Federal Register* at 65 *Fed. Reg.* 17946 (April 5, 2000) and the *Official Gazette* at 1233 *Off. Gaz. Pat. Office* 121 (April 25, 2000). This rule implements Subtitle E of the AIPA by proposing procedures for an application publication system. The comment period for this rulemaking expired May 22, 2000. The next step is to reconsider the proposed procedures and to adopt procedures for the application publication system by undertaking a final rulemaking process. Publication of the final rulemaking is anticipated before September 5, 2000, with an effective date for the rule changes being November 29, 2000.

The USPTO also anticipates publishing Examination Guidelines in the *Official Gazette* in view of the changes to 35 U.S.C. § 102(e) to identify which applications are subject to the new prior art created by the amendment, and the other effects of the changes. The USPTO does **not** anticipate publishing any guidance to define the terms “substantially identical” or “actual notice” as those terms are used in the AIPA provisions related to provisional rights.

The proposed rules provide for the statutory requirement of publication of most applications filed on or after November 29, 2000, 18 months after the earliest effective filing date or priority date claimed by the application. An applicant who has not and will not file in a foreign country or under an international agreement that publishes applications after an 18 month period from the effective filing or priority date of applications, may request nonpublication, but the

request must be submitted with the application filing. Rescission of this nonpublication request may be done at any time, and must be done to avoid abandonment of the application should a foreign filing be made after making the request.

The rules require use of the USPTO's Electronic Filing System (EFS) for requests that applications be published as redacted (eliminating matter disclosed only in the U.S. version of the application), or as amended. EFS is also required for any request for voluntary publication (for publication of an application filed before November 29, 2000) or any republication request for applications previously published when an applicant desires an additional, later publication for amendments which have been made. Use of EFS will enable the USPTO to provide for the publication of applications other than as filed after November 29, 2000, without substantial delays that would otherwise be caused by removing the applications from the examination process.

The rules also propose to require that all benefit claims under 35 USC 119, 120, 121, and 365 be made within the later of four months from filing or 16 months from the filing date of the priority application. The rules, however, provide for unintentionally delayed claims for priority or benefit of a prior application's filing date to be accepted after that time period on petition.

Following publication, submission of a limited number of printed patents or publications by third parties is proposed for a two-month period. Additionally, the USPTO proposes to provide access to the file history of published applications by providing photocopies of file wrappers on request. While not part of the rules, access to the electronic records of papers entered into the file wrapper of published patent applications is planned.

### **Subtitle F**

Subtitle F is entitled "Optional Inter Partes Reexamination Procedure Act of 1999." This subtitle provides for expanded participation of a third party during the reexamination of a patent throughout the proceedings through a final decision by the Board of Patent Appeals and Interferences as an alternative option to *ex parte* reexamination. The third party, however, does not have a right to participate in any appeal to the Court of Appeals for the Federal Circuit. The subtitle also imposes significant estoppel provisions after the conclusion of proceedings should a party to the *inter partes* reexamination proceedings subsequently litigate any fact that was, or could have been, determined during the reexamination proceedings. While the *inter partes* provisions of the subtitle were in effect on November 29, 1999, the provisions only apply to

patents that issue from applications filed on or after November 29, 1999.

A notice of proposed rulemaking entitled “Rules to Implement Optional Inter Partes Reexamination Proceedings” was published in the *Federal Register* at 65 *Fed. Reg.* 18154 (April 6, 2000) and the *Official Gazette* at 1234 *OG* 93 (May 23, 2000). This rule proposes to implement Subtitle F of the AIPA by proposing procedures for *inter partes* reexamination which becomes effective for patents issued from original applications filed on or after November 29, 1999. The rule also implements miscellaneous changes in *ex parte* reexamination practice. The comment period for this rulemaking expired June 12, 2000. The next step is to reconsider the proposed procedures and to adopt procedures for *inter partes* reexamination practice by undertaking a final rulemaking process. Publication of the final rulemaking is anticipated before September 5, 2000, with an effective date for the rule changes being two months thereafter.

Following a request for *inter partes* reexamination, an examiner must determine whether to order the reexamination. Unlike *ex parte* reexamination proceedings, an office action will typically accompany an order of *inter partes* reexamination. The office action must address all proposed rejections made in the request by either adopting the rejection or expressly declining to adopt the rejection and by giving the rationale of the examiner for not adopting the proposed rejection. If the action indicates allowability of all of the claims, the action should be one “closing prosecution” which is discussed below. Following the first action, the rules propose an entirely new procedure by establishing that the third party may once file comments on any response filed by the patent owner. Thereafter, the examiner reconsiders the first office action in view of all of the comments by both parties, and prepares a second office action addressing all of the claims, and all of the comments. This second action will typically be made an action “closing prosecution” which is made when the issues in the reexamination proceedings are clear. After this action the third party and patent owner again submit comments on the office action and comments on the other party’s submission. Thereafter, the examiner may issue a “Examiner’s Right of Appeal Notice” which must address the comments made in response to the action closing prosecution or the examiner may reopen prosecution by preparing a new office action.

After the “Examiner’s Right of Appeal Notice” either the patent owner or third party, or both, may appeal the decision of the examiner to the Board of Patent Appeals and Interferences. Importantly, the third party may appeal any decision to not make or sustain a rejection proposed by the third party. The appeal phase will include

a right of either the patent owner or third party to file a reply brief in opposition to the original brief of the opposing party. The examiner would thereafter prepare an examiner's answer responsive to the positions asserted by the patent owner and the third party on both patentability and non-sustainability of rejections not adopted by the examiner. Following final decision by the Board of Patent Appeals and Interferences, only the patent owner may file an appeal to the Court of Appeals for the Federal Circuit.

### **Subtitle H**

Subtitle H is entitled "Miscellaneous Patent Provisions." Of greatest importance within the USPTO, the subtitle amended both the treatment of provisional applications and the treatment of commonly owned or assigned patents as prior art. Statutory authority to treat a provisional patent application as a nonprovisional patent application was provided without regard to the presence of a claim. The copendency requirement between a provisional and a nonprovisional application seeking to claim the benefit of priority of the provisional application was eliminated. Additionally, for most provisional applications, if the 12-month pendency period ends on a non-business day, the period is extended to the next business day.

Subtitle H also provides for the exclusion of commonly owned or assigned patents used in obviousness rejections applied against the later invention if the patent is available as prior art only under 35 USC 102(e).

The USPTO implemented the changes to the provisional application practice in an interim rule entitled "Changes to Application Examination and Provisional Application Practice" which was published in the *Federal Register* at 65 *Fed. Reg.* 14865 (March 20, 2000) and the *Official Gazette* at 1233 *Off. Gaz. Pat. Office* 47 (April 11, 2000). The comment period for this rulemaking expired May 19, 2000. The next step is to reconsider the interim rule in view of the public comments, and adopt final changes by undertaking a final rulemaking process. Publication of a final rule is expected by August 15, 2000. The effective date for any final rule will be the date of publication of the final rule.

A notice entitled "Guidelines Concerning the Implementation of Changes to 35 USC 102(g) and 103(c) and the Interpretation of the Term 'Original Application' in the American Inventors Protection Act of 1999" was published in the *Official Gazette* at 1233 *Off. Gaz. Pat. Office* 54 (April 11, 2000). This notice provides guidance on the position of the USPTO concerning the applications that are eligible for the new exclusion to certain commonly owned or assigned patents.

## Quick Reference to Effective Dates of AIPA

P.L.106-113 (S.1948 as incorporated into H.R.3194 and signed into law on November 29, 1999)

| Section Number/Description  | Effective Date    |
|---|-------------------|
| <u>Subtitle A - Inventors Rights/Invention Promotion Services</u>                                       |                   |
| 4102/4103 (inventor's rights)   | January 28, 2000  |
| <u>Subtitle B - Patent and Trademark Fee Fairness</u>   |                   |
| 4202/4206 (fee adjustment - patents)  | December 29, 1999 |
| 4203/2406 (trademark fees)  | November 29, 1999 |
| New trademark fees effective 1/03/00 per rulemaking.  |                   |
| 4204-4205/4206 (fee study, PTO funding)   | November 29, 1999 |
| <u>Subtitle C - First Inventor Defence/Methods of Doing or Conducting Business</u>                      |                   |
| 4302/4303   | November 29, 1999 |
| <u>Subtitle D - Patent Term Guarantee</u>   |                   |
| 4402/4405 (patent term adjustment)  | May 29, 2000      |
| 4403/4405 (continued examination of applications)   | May 29, 2000      |
| 4404/4405 (technical clarification to 156(c))   | May 29, 2000      |
| <u>Subtitle E - Domestic Publication of Patent Applications Published Abroad</u>                        |                   |
| 4502/4508 (publication at 18 months)  | November 29, 2000 |
| 4503/4508 (time for claiming benefit of earlier filing date)  | November 29, 2000 |
| 4504/4508 (provisional rights based on actual notice of published application)                          | November 29, 2000 |
| 4505/4508 (prior art effect of published applications)  | November 29, 2000 |
| 4506/4508 (cost recovery for publication)   | November 29, 2000 |
| 4507/4508 (conforming amendments)   | November 29, 2000 |
| <u>Subtitle F - Optional Inter Partes Reexamination</u>   |                   |
| 4604/4608(a) (optional inter partes reexam)   | November 29, 1999 |
| 4605(a)/4608(b) (conforming amendments (revival fees))  | November 29, 2000 |
| 4605(b)/4608(a) (conforming amendments (appeals))   | November 29, 1999 |
| 4606/4608(a) (report to Congress)   | November 29, 1999 |
| 4607/4608(a) (estoppel provisions)  | November 29, 1999 |
| <u>Subtitle G - Patent and Trademark Office</u>   |                   |
| 4711-4720/2731 (various)  | March 29, 2000    |
| <u>Subtitle H - Miscellaneous Patent Provisions</u>   |                   |
| 4801/4801 (provisional applications - to permit conversion and to eliminate the copendency requirement) | November 29, 1999 |
| 4802 (international applications)   | November 29, 1999 |
| 4803 (certain limitations on damages (med. meth.))  | November 29, 1999 |
| 4804 (electronic filing and publication)  | November 29, 1999 |
| 4805 (study and report on biological deposits)  | November 29, 1999 |
| 4806 (prior invention - 35USC102(g))  | November 29, 1999 |
| 4807/4807 (prior art exclusion for certain commonly assigned patents)                                   | November 29, 1999 |
| 4808 (exchange of copies of patents with FCs)   | November 29, 1999 |

# Faces of the USPTO

## *Kimberly H. Walton*

was appointed deputy chief administrative officer for human resources, civil rights and administrative services on April 3, 2000. She is a key member of the chief financial officer/chief administrative officer's immediate policy planning group and participates in the formulation and review of policy and planning determinations affecting the entire USPTO.



Prior to the USPTO, Walton advised Secretary of Commerce William Daley and the Commerce Department's senior staff on all aspects of equal opportunity, on matters relating to non-discrimination cases, on concerns that relate to civil rights and diversity, and on various ways to advance affirmative employment. She also chaired the department's Diversity Council. Before Commerce, Walton was an attorney with the Equal Employment Opportunity Commission.

Walton's priorities are:

- revamping the recruitment process and addressing retention issues;
- working with and making an overall positive contribution on partnership issues at the USPTO; and
- ensuring that the chief financial officer/chief administrative officer organization focuses on providing first-class customer service.

Walton holds a J.D. from Catholic University, Columbus School of Law, and she studied psychology at the University of Tennessee and Columbia University. She is a member of the District of Columbia Bar. Walton received the Departmental Silver Medal and two Bronze Medals, the second and third highest awards and honors presented at the Commerce Department.

# Roundtable on Business Method Patents: The Debate Continues

*by Jennifer Lucas, Office of Legislative and International Affairs*

On July 27, the USPTO held a roundtable on computer-implemented business method patents, a topic that has generated many debates in recent months.

Led by moderator Jim Crowne, who is the managing editor for *BNA's Patent, Trademark, And Copyright Journal*, 24 panelists were brought together to discuss the history behind computer-implemented business method patents and to identify ways to improve the USPTO's current examination approach to applications for this type of invention. More than 200 audience members observed the discussions.

The USPTO was represented by three panelists: Q. Todd Dickinson, under secretary of Commerce and director of the United States Patent and Trademark Office; Nicholas Godici, commissioner for patents; and Esther Kepplinger, deputy commissioner for patent operations. The other 21 panelists represented a cross-section of stakeholders in the business method patent debates, including patent attorneys, representatives from academia and trade associations, consumer advocates, and patent holders, to name a few.

The panelists kept up a lively discussion during the day-long roundtable on a variety of topics, but two topics were at the forefront of everyone's mind and continued to come up throughout the day. The first topic was how the USPTO examined computer-implemented business methods, with a focus on where examiners were searching for prior art. The second was whether business methods should be patented in the first place. The panelists also discussed the impact of these types of patents on the innovation, evolution, and development of electronic commerce. No conclusions were reached, but the panelists enjoyed debating the various issues.

In conjunction with the roundtable, the USPTO released a White Paper outlining the history and current USPTO practices concerning computer-implemented business method patents in Class 705, that is available at the USPTO Web site.

The USPTO held the roundtable as a part of the industry outreach portion of its Business Methods Patent Initiative, which it announced in March. With respect to industry outreach, the USPTO also is working to form customer partnerships with interested industries and is making efforts to obtain industry feedback on issues relating to prior art. In addition, the initiative calls for quality controls, including enhanced technical training, revision of the examination guidelines, and expanded prior art search requirements.

The panel participants were:

Robert Armitage, Eli Lilly & Co.  
Pamela I. Banner, Banner & Witcoff, LTD  
Eric M. Goldberg, American Insurance Association  
Albert Keyack, DirectWeb, Inc.  
Jeffrey R. Kuester, Thomas, Kayden, Horstemeyer & Risley, LLP  
Keith Kupferschmid, Software & Information Industry Association  
Scott Kursman, Securities Industry Association  
Jeffrey P. Kushan, Powell, Goldstein, Frazer & Murphy, LLP  
Ron Laurie, Skadden, Arps, Slate, Meagher & Flom, LLP  
Joshua Lerner, Harvard Business School  
Nancy Linck, Guilford Pharmaceuticals  
James Love, Consumer Project on Technology  
Peter Menell, University of California School of Law  
Rick Nydegger, Wortman, Nydegger & Seeley/AIPLA  
Tim O'Reilly, O'Reilly Publishing  
Jerry A. Riedinger, Perkins Coie  
Patrick Romain, Merrill Lynch  
Scott C. Sander, SIGHTSOUND.COM  
Glenn S. Tenney, Institute for Electrical & Electronics Engineers  
Jay Thomas, George Washington University Law School  
Steven I. Wallach, Pennie & Edmonds, LLP

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# Patenting Human Gene-Based Inventions

by Margaret M. Parr, Biotechnology Practice Specialist, and  
Tod Preston, Office of Legislative and International Affairs

For more than a decade, the patenting of inventions in cutting-edge biotechnology has been a subject of debate in the legal, academic and business communities. Much of this debate has centered on just what biotechnology products and methods should be patentable in the United States and what the impact of those patents will be on research and development in agriculture and human health. More recently, the debate has focused on the question of whether human genes (nucleic acids that code for proteins) and other inventions related to the human genome should be patentable.

## **What biological materials are eligible to be patented in the U.S?**

The basis for the U.S. patent system is set forth in the United States Constitution which gives Congress the power “*to promote the progress of science and useful arts by securing for limited times to . . . inventors the exclusive right to their . . . discoveries.*” Patent rights provide incentives to inventors that have resulted in the growth of many new technologies that have fueled the American economy and improved our quality of life. The grant of exclusive rights is a *quid pro quo* for the technical disclosure of the invention that might otherwise have been kept secret. However, not every invention is eligible for patent protection.

Prior to granting a patent, the USPTO examines each patent application to determine whether it meets four basic requirements set forth in Title 35 of the U.S. Code. The claimed invention must be subject matter eligible for patent in the U.S. and must have utility (35 USC § 101). The claimed invention must be novel (35 USC § 102). The claimed invention must not have been obvious to a person having ordinary skill in the technology at the time the invention was made (35 USC § 103). The invention must be fully and unambiguously disclosed in the text of the patent application, so that a skilled practitioner would be able to practice the claimed invention (35 USC § 112).

With respect to the first statutory requirement, 35 U.S.C. § 101 states that any person who “invents or discovers any new and useful . . . composition of matter, or any new and useful improvement thereof, may obtain a patent . . .” subject to the conditions and

requirements of the law.

There is a tendency among the patent system's critics to assert that genetic material cannot be patented because it is found naturally in our bodies. However, genes are basically complex chemicals and chemicals that have been isolated and purified from naturally-occurring sources have long been held to be patentable. For example, the Fourth Circuit stated in 1958 in a case involving naturally occurring vitamin B12 compounds that "There is nothing in the language of the [1952] Act which precludes the issuance of a patent upon a 'product of nature' when it is a 'new and useful composition of matter' .... All of the tangible things ... for which patent protection is granted are products of nature in the sense that nature provides the source materials." (Merck & Co., Inc. v. Olin Mathieson Chem. Corp., 253 F.2d 156, 161, 163). Two decades later, the Court of Customs and Patent Appeals ruled in 1979 that a biologically pure bacterial culture was patentable since the culture did not exist in nature in a biologically pure form and could only be produced in a laboratory under carefully controlled circumstances. (In re Bergy, 596 F.2d 952, 201 U.S.P.Q. 352 (CCPA 1979))

The most significant ruling on the patentability of biological products occurred a year later, in the Supreme Court's landmark decision in Diamond v. Chakrabarty, 447 U.S. 303, 309, 206 U.S.P.Q. 193, 197 (1980). In that decision, which found that genetically engineered bacteria were patentable, Chief Justice Burger noted that "Congress intended statutory subject matter to 'include anything under the sun that is made by man.'

*"[Chakrabarty's] microorganism plainly qualifies as patentable subject matter. His claim is not to a hitherto unknown natural phenomenon, but to a nonnaturally occurring manufacture or composition of matter—a product of human ingenuity 'having a distinctive name, character [and] use.' (Hartranft v. Wiegmann, 121 US 609, 615 (1887)) ... [T]he patentee has produced a new bacterium with markedly different characteristics from any found in nature and one having the potential for significant utility. His discovery is not nature's handiwork, but his own; accordingly it is patentable subject matter under §101."*

The Supreme Court ruling in the Chakrabarty decision paved the way for a variety of patents involving living materials, including the first transgenic animal patent to the now-famous Harvard "oncomouse," a mouse genetically engineered to be more susceptible to tumor growth. Many patents have since issued on other genetically engineered plants and animals, fueling the biotechnology industry. Consistent with the findings in Chakrabarty, the courts have consistently ruled that genomic products and their mutations fall

within the statutory categories of compositions of matter and manufactures. (See, e.g., In re O'Farrell, 853 F.2d 894, 7 U.S.P.Q.2d 1673 (Fed. Cir. 1988) and Amgen, Inc. v. Chugai Pharm. Co., Ltd., 927 F.2d 1200, 18 U.S.P.Q.2d 1016 (Fed. Cir. 1991)). However, in order to be patentable, they must not be in their naturally occurring state, and their invention must be the result of human intervention. In other words, the gene must be isolated and purified from its natural environment.

A gene patent claim covers a specific chemical compound, a nucleic acid. The chemical and physical structure and properties of the nucleic acid differ from what is found in the chromosome of an individual but are relevant to a diagnostic or therapeutic application. A gene patent does not protect a gene as it exists in a human chromosome.

The USPTO has issued hundreds of patents to products extracted from the human body for pharmaceutical or diagnostic use, including clot-busting proteins to treat stroke, cancer antigens for detection of cancer, and antibodies to treat infection. Human growth hormone was originally isolated from human pituitary glands, as were some vitamins.

Patents provide significant incentives for genomic research. It was the cloning and subsequent patenting of the human insulin gene that allowed researchers to synthesize genuine human insulin in the laboratory using recombinant DNA technology. This approach results in more reliable insulin protein and reduces complications than can occur from a reaction to animal insulin. Indeed, there are so many chemicals in the human body that, if we ruled them all off limits to patenting, we would rule out an extraordinary number of valuable and important inventions.

### **Utility and Written Description Guidelines**

The USPTO is currently reassessing two criteria of patentability - the requirements that an invention have a specifically identified usefulness or "utility" under 35 U.S.C. 101, and that the disclosure of the invention in the patent application demonstrate that the inventor is in possession of what is being claimed by the applicant under the written description requirement of 35 U.S.C. § 112, first paragraph. Certainly, a key issue for determining whether a genomic invention is patentable is the question of utility. As with any other invention, a nucleic acid must be useful in order to be patentable. Raw DNA sequence data, such as that recently generated by the Human Genome Project and various corporations, is not patentable subject matter.

Genomic patent specifications are scrutinized for an adequate written description, sufficiency of the disclosure, and enabled utilities, in accordance with the standards set forth by the USPTO's reviewing courts. In order to ensure the highest standards of utility, the USPTO published "Revised Interim Utility Examination Guidelines" and "Revised Interim Written Description Guidelines" in the Federal Register on December 21, 1999. Companion training documents illustrating how patent examiners are to apply the guidelines to specific fact patterns were also published on the USPTO Website ([www.uspto.gov](http://www.uspto.gov)) on March 1, 2000. The USPTO is currently finalizing these guidelines, based upon public comments, and we expect to publish them by early this fall.

The new utility guidelines require patent applicants to explicitly identify, unless already well-established, a specific, substantial and credible utility for all inventions. In effect, the USPTO has raised the bar to ensure that patent applicants demonstrate a "real world" utility. One simply cannot patent a gene itself without also clearly disclosing a use to which that gene can be put.

An asserted utility is **credible** unless the logic underlying the assertion is seriously flawed, or the facts upon which the assertion is based are inconsistent with the logic underlying the assertion. For example, at least some nucleic acids might be used as probes, chromosome markers, or diagnostic markers. Therefore, the *per se* credibility of assertions regarding the use of nucleic acids is not usually questioned. However, even if credible, at least one asserted utility must also be both **specific** and **substantial**.

A utility is **specific** when it is particular to the subject matter claimed. For example, a polynucleotide said to be useful simply as a "gene probe" or "chromosome marker" does not have specific utility in the absence of a disclosure of a particular gene or chromosome target. Similarly, a general statement of diagnostic utility would ordinarily be insufficient to meet the requirement for a specific utility in the absence of an identification of what condition can be diagnosed.

A **substantial** utility is one that defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities. For example, basic research that uses a claimed nucleic acid simply for studying the properties of the nucleic acid itself does not constitute a substantial utility.

In general, if a partial nucleic acid sequence is useful for diagnosis of a particular disease, then the sequence would likely meet the

utility requirement and patent protection commensurate in scope with the disclosure would be granted assuming the other statutory requirements for patentability are met. As increased amounts of information are provided both about the nature of the nucleic acid and its uses, broader coverage would be granted.

The USPTO has received significant positive feedback that these new guidelines set the utility standard at an appropriate level to ensure incentives for both research and the efficient dissemination of valuable data. For example, Dr. Francis Collins, Director of the National Human Genome Research Institute, has said that the new utility guidelines are “quite reassuring in terms of making sure that we end up with an outcome where the patent system is used to provide an incentive for research and not a disincentive.” Dr. Craig Venter, the President and Chief Scientific Officer of Celera Genomics Corporation, recently stated that he was “pleased to see [the USPTO] is raising the bar” on gene patents.

The written description requirement is designed to ensure that the inventor had actual possession of what is being claimed as the invention. This requirement as it relates “gene” claims was the subject of the decision of *The Regents of the University of California v. Eli Lilly and Company*, 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997), *cert. denied*, 523 U.S. 1089 (1998). The Federal Circuit addressed the question of whether possession of only one species of a gene entitled the discoverer of that gene to claim possession of analogous genes in other species. The written description guidelines encourage disclosure of a reduction to practice, a reduction to drawings or disclosure of sufficient relevant identifying characteristics of the invention claimed in a patent application to ensure the possession requirement is met.

### **Patents and Emerging Technologies**

Some have expressed concerns that patents inherently impede access to new technology, but history provides little evidence that this is the case. For example, consider the broad U.S. Patents 4,237,224 and 4,468,464, issued to inventors Cohen and Boyer in 1980 and 1984. These patents cover a significant amount of the subject matter currently being used in biological research, including recombinant DNA materials and methods of making and using such materials. Owned by Stanford University and widely licensed for nominal fees, these patents are considered to be some of the most profitable patents ever to issue in biotechnology. This profitability is largely due to their widespread use in the advancement of biological research. Indeed, the dominance of these patents did not stifle research, but served instead to spur innovation by providing the incentives of patent protection.

In reality, patents have been integral to the United States' biotech industry's growth into the powerhouse it is today. According to the Biotechnology Industry Association, the biotechnology industry has doubled in size between 1993 and 1999. In 1999, the biotechnology industry generated 437,400 U.S. jobs, \$47 billion in additional revenues, \$11 billion in research & development spending and \$10 billion in tax revenues.

While the patent system provides protection to inventors for their innovations, it also provides for dissemination of information and technology that might otherwise be maintained as trade secrets. The biotechnology and pharmaceutical industries are some of the most research-intensive industries in existence. In supporting that research, the private sector often looks to the patent system to provide the market exclusivity necessary to attract and recoup their investments in the development of new biological products and to prevent exploitation of proprietary technology. Without the funding and incentives that are provided by the patent system, research into the basis of genetic diseases and the development of tools for the diagnosis and treatment of such diseases would be significantly curtailed. Moreover, genomic patents enable companies, especially smaller enterprises, to raise the capital needed to bring beneficial products to the marketplace or fund further research.

### **Conclusion**

Currently, over 20,000 applications relating to genes are pending before the USPTO. Since the first gene related applications were filed, approximately 6,000 patents have issued which are drawn to full-length genes from human, animal, plant, bacterial and viral sources. Of these 6,000 patents, over 1,000 are specifically drawn to human genes and human gene variations that distinguish individuals.

The USPTO is committed to ensuring that our practices and policies promote the innovation and dissemination of new technologies. The patenting of genomic inventions is consistent with U.S. law and with USPTO practice. Just as the patent system has nurtured the development of telephony, aeronautics, computers, and a host of other industries, the balance it strikes between generating intellectual property and disseminating those technologies will ensure that new discoveries in genomics lead to healthier, longer lives for all of humankind.

# USPTO Customer Outreach Lecture Series

In the interest of providing better service to its customers, the U.S. Patent and Trademark Office operates a secure VideoConference Center. Linked to its three Partnership Patent and Trademark Depository Libraries, it provides board hearings, examiner interviews and lectures. Contact your closest partnership library for more information and local times.

| <u>Schedule Date</u> | <u>Topic</u>                    | <u>Lecturer</u>              | <u>Duration Of Lecture</u> | <u>Time (EDT)</u> |
|----------------------|---------------------------------|------------------------------|----------------------------|-------------------|
| 9/12/00              | USC 102                         | Tom Will                     | 2 Hours                    | 1pm – 3pm         |
| 9/14/00              | Affidavits 37 CFR 1.131 & 1.132 | Dave Lacey                   | 2 Hours                    | 1pm – 3pm         |
| 9/19/00              | Re-Issue / Re-Exam              | Ken Schor /<br>Joe Narcavage | 2 Hours                    | 1pm – 3pm         |
| 9/21/00              | 35 USC 103                      | David Moore                  | 2 Hours                    | 1pm – 3pm         |

Sunnyvale Center for Innovation, Invention and Ideas  
Sunnyvale, California  
Phone: (408) 730-7290

Great Lakes Patent and Trademark Center  
Detroit, Michigan  
Phone: (313) 833-3379

South Central Intellectual Property Partnership at Rice University  
Houston, Texas  
Phone: (713) 348-5196

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The United States Patent and Trademark Office is currently holding free, one-day, educational workshops across the country at Patent and Trademark Depository Libraries detailing implementation of the American Inventors Protection Act of 1999 (AIPA) and introducing the agency's electronic commerce initiatives.

The **Patents 2000 Customer Outreach Program** is designed to help registered patent attorneys/agents, legal staff and independent inventors understand the impact of the AIPA, which became law in late 1999.

The highlights of the electronic commerce segment are Patent Application Information Retrieval (PAIR) - How to access information about your patent application or any issued patents/published application via the Internet; Electronic Filing System (EFS) - How to file a patent application online; Changes to PAIR and EFS to support implementation of the AIPA and whether or not you will need to use PAIR and EFS as a result of AIPA implementation; and Public Key Infrastructure (PKI) - How the USPTO protects your application information on the Internet.

In each city, there will be two workshops, one planned for attorneys and large corporations and one planned for independent inventors. The workshops will be presented as interactive lectures with ample opportunity for questions and answers.

**Reservation and contact information for USPTO's Patents 2000 Customer Outreach Program workshops follows.**

The Free Library of Philadelphia; Philadelphia, PA  
August 9 and 10  
Contact: (215) 686-5331

Science, Industry and Business Library, New York Public Library;  
New York, NY  
September 7 and 8  
Contact: (212) 592-7044

Fondren Library, Rice University; Houston, TX  
September 14 and 15  
Contact: (713) 348-5483; [scippr@rice.edu](mailto:scippr@rice.edu)

USPTO; Arlington, VA  
September 19 and 20  
Contact: (703) 305-8341

Boston Public Library; Boston, MA  
September 26 and 27  
Contact: (617) 536-5400 ext. 265

Engineering Library, University of Washington; Seattle, WA  
October 16 and 17  
Contact: (206) 685-8371; [englib@u.washington.edu](mailto:englib@u.washington.edu)

Chicago Public Library; Chicago, IL  
October 30 and 31  
Contact: (312) 747-4477

Milwaukee Public Library; Milwaukee, WI  
November 2 and 3  
Contact: (414) 286-3000

For more information about the Patents 2000 Customer Outreach Program, please go to [www.uspto.gov](http://www.uspto.gov) and click on American Inventors Protection Act or the Patent Electronic Business Center.

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